KETOTIFEN FUMARATE- ketotifen fumarate solution/ drops
Direct_Rx

Ketotifen Fumarate

Ketotifen 0.025%
(equivalent to ketotifen fumerate 0.035%)

Antihistamine

For the temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair and dander.

For external use only

Do not use

- if you are sensitive to any ingredient in this product
- if solution changes color or becomes cloudy
- to treat contact lens related irritation

When using this product

- remove contact lenses before use
- wait at least 10 minutes before re-inserting contact lenses after use
- do not touch tip of container to any surface to avoid contamination
- replace cap after each use

Stop use and ask doctor if you experience any of the following:

- eye pain
- changes in vision
- redness of the eyes
- itching that worsens or lasts more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Adults and children 3 years and older: put 1 drop in the affected eye(s) twice daily, every 8-12 hours, no more than twice per day.

Children under 3 years of age: consult a doctor

Store at 4-25°C (39-77°F)

benzalkonium chloride 0.01%, glycerin, hydrochloric acid and/or sodium hydroxide, water for injection

Toll Free Product Information
Call: 1-800-645-2158

Distributed by:
RUGBY® LABORATORIES
17177 N Laurel Park Drive
Suite 233, Livonia, MI 48152
www.rugbylaboratories.com
Product of Italy

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72189-461(NDC:0536-1252)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
KETOTIFEN FUMARATE (UNII: HBD503WORO) (KETOTIFEN - UNII:X49220T18G)	KETOTIFEN	0.25 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72189-461-05	5 mL in 1 CARTON; Type 0: Not a Combination Product	04/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA021996	04/05/2023	

Labeler - Direct_Rx (079254320)

Registrant - Direct_Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct_Rx		079254320	relabel(72189-461)

Revised: 4/2023 Direct_Rx